



Revised 02/20/01

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter M. Goodwin et al.

Docket No.: S-94,652

Serial No.: 09/862,855

Examiner:

Filed : May 22, 2001

Art Unit:

For : RAPID HAPLOTYPING BY SINGLE MOLECULE DETECTION

Assistant Commissioner for Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.56, 1.97, AND 1.98

Sir:

The documents listed below, copies attached, may be material to the examination of the subject application and is therefore submitted in compliance with the duty of disclosure defined in 37 CFR 1.56.

1. Stanton, Jr., "Probes for variance detection," US Patent 6,183,958, Issued, Feb. 6, 2001.
2. Goelet et al., "Method for determining nucleotide identity through extension of immobilized primer," US Patent 6,004,744, Issued, Dec. 12, 1999.
3. Mathies et al., "Capillary array confocal fluorescence scanner and method," US Patent 5,274,240, Issued, Dec. 28, 1993.

CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

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☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, DC 20231.

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Date

July 20, 2001

Ray G. Wilson

(type or print name of person certifying)

4. Mathies et al., "Multiple tag labeling method for DNA sequencing," US Patent 5,436,130, Issued, July 25, 1995.
5. Conrad, "Probes comprising fluorescent nucleosides and uses thereof," US Patent 5,652,099, Issued, July 29, 1997.
6. Mathies et al., "Fluorescent labels and their use in separations," US Patent 5,654,419, Issued, August 5, 1997.
7. Cai et al., (2000) "Flow cytometry-based minisequencing: A new platform for high-throughput single-nucleotide polymorphism scoring," *Genomics* **66**, 135-143.
8. Davidson S. (2000) " Research suggests importance of haplotypes over SNPs" *Nat. Biotech.* **18**: 1134-1135.
9. Drysdale C.M. et al. (2000) "Complex promoter and coding region beta(2)-adrenergic receptor haplotypes alter receptor expression and predict in vivo responsiveness" *PNAS* **97**: 10483-10488.
10. Taton, T.A. et al. (2000) "Haplotyping by force." *Nature Biotechnology* **18**: 713-713.
11. Wahlestedt C. et al. (2000) "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," *PNAS* **97**: 5633-5638.
12. Wooley A.T. et al. (2000) "Direct haplotyping of kilobase-size DNA using carbon nanotubes probes," *Nature Biotechnology* **18**: 760-763.
13. Brookes A.J. et al (1999), "The essence of SNPs," *Gene* **234**:177-186.
14. Chen X.N. et al. (1999) "Homogeneous genotyping assays for single nucleotide polymorphisms with fluorescence resonance energy transfer detection," *Genetic Analysis Biomolecular Engineering* **14** (5-6): 157-163.
15. Hodge S.E. et al (1999). "Loss of information due to ambiguous haplotyping of SNPs". *Nat. Genetics.* **21**:360-361.
16. Lyamichev, V. et al. (1999) "Polymorphism Identification and quantitative detection of genomic DNA by invasive cleavage of oligonucleotide probes," *Nat. Biotechnol.* **17**: 292-296.
17. Kwok P. (1999). "Single nucleotide polymorphism libraries: Why and how are we building them?" *Molecular Medicine Today* **5**:538-543.

18. Orum, H. et al. (1999) "Detection of the Factor V Leiden mutation by direct allele specific hybridization of PCR amplicons to photoimmobilized locked nucleic acids," *Clinical Chemistry* **45**:1898-1905.
19. VanDongen, J.M. et al. (1999), "Standardized RT-PCR analysis of fusion gene transcripts from chromosome aberrations in acute leukemia for detection of minimal residual disease: Report of the BIOMED-1 Concerted Action: Investigation of minimal residual disease in acute leukemia," *Leukemia* **13**: 1901-28.
20. Vet, J. A. M. et al. (1999) "Multiplex detection of four pathogenic retroviruses using molecular beacons," *Proceedings of the National Academy of Sciences of the United States of America* **96**(11): 6394-6399.
21. Vogelstein, B. (1999) " Digital PCR," *PNAS* **96**(16): 9236-9241.
22. Cai, H. et al. (1998). "Flow cytometry-based hybridization and polymorphism analysis," *Proc. SPIE* **3256**: 171-177.
23. Koshkin, A.A. et al. (1998) "LNA (Locked Nucleic Acids): synthesis of the adenine, cytosine, guanine, 5-methylcytosine, thymine and uracil bicyclonucleoside monomers, oligomerisation, and unprecedented nucleic acid recognition" *Tetrahedron* **54**: 3607-3630.
24. Kostrikis, L. G. et al. (1998). "Molecular beacons : Spectral genotyping of human alleles," *Science* **279**(5354): 1228-1229.
25. Landegren, U. et al. (1998). "Reading bits of genetic information : methods for single-nucleotide polymorphism analysis," *Genome Research* **8**(8): 769-776.
26. Luthra, R. et al. (1998) "Novel 5'-exonuclease-based real-time PCR assay for the detection of T(14-18)(Q32-Q21) in patients with follicular lymphoma," *American Journal of Pathology* **153**(1): 63-68.
27. Tyagi, S. et al. (1998) "Multicolor molecular beacons for allele discrimination," *Nature Biotechnology* **16**(1): 49-53.
28. Castro, A. et al. (1997). "Single-molecule detection of specific nucleic-acid sequences in unamplified genomic DNA," *Analytical Chemistry* **69**(19): 3915-3920.

29. Castro, A. et al. (2000). "Ultrasensitive, direct detection of a specific DNA sequence of *Bacillus anthracis* in solution," *The Analyst Communication* **125**: 9-11.
30. Wooley A.T. et al. (2000) "Direct haplotyping of kilobase-size DNA using carbon nanotubes probes," *Nature Biotechnology* **18**: 760-763.
31. Ha, T. et al. (1996) "Probing the interaction between two single molecules: Fluorescence resonance energy transfer between a single donor and a single acceptor," *Proc. Natl. Acad. Sci.* **93**: 6264-6268.
32. Look, A.T. (1997) "Oncogenic transcription factors in the human acute leukemias" *Science* **278**: 1059-64.
33. Syvanen, A.C. et al. (1997) "Minisequencing: a specific tool for DNA analysis and diagnostics on oligonucleotide arrays" *Genome Res.* **7**: 606-614.
34. Schwille, P. et al. (1997) "Dual-color fluorescence cross-correlation spectroscopy for multicomponent diffusional analysis in solution" *Biophysical Journal* **72**: 1878-1886.
35. Goodwin, P. M. et al. (1996). "Single-molecule detection in liquids by laser-induced fluorescence," *Accounts of Chemical Research* **29**(12): 607-613.
36. Keller, R. A. et al. (1996) "Single-molecule fluorescence analysis in solution." *Applied Spectroscopy* **50**(7): A12-A32.
37. Kinjo, M. et al. (1995) "Ultrasensitive hybridization analysis using fluorescence correlation spectroscopy," *Nucleic Acids Research* **23**(10): 1795-1799.
38. Eigen, M. et al. (1994) "Sorting single molecules: Application to diagnostics and evolutionary biotechnology" *PNAS* **91**: 5740-5747.
39. Wittung, P. et al. (1994) "DNA-like double helix formed by peptide nucleic acid," *Nature* **368**: 561-563.
40. Egholm, M., et al. (1993) "PNA hybridizes to complementary oligonucleotides obeying the Watson-Crick hydrogen bonding rules" *Nature* **365**: 566-568.

41. Lee, L. G. et al. (1993) "Allelic discrimination by nick-translation PCR with fluorogenic probes," *Nucleic Acids Research* **21**(16): 3761-3766.
42. Orum, H. et al. (1993) "Single-base pair mutation analysis by PNA directed CR Clamping," *Nucleic Acids Research* **21**(23): 5332-5336.
43. Rigler, R. et al. (1993). "Fluorescence correlation spectroscopy with high count rate and low-background: analysis of translational diffusion," *Eur. Biophys. J.* **22**(3):169-175.
44. Zhang L. (1992) "Whole genome amplification from a single cell: Implications for genetic analysis," *PNAS* **89**:5847-5851.
45. Holland, P. M. et al. (1991) "Detection of specific polymerase chain-reaction product by utilizing the 5'-3' exonuclease activity of *Thermus-Aquaticus* DNA-polymerase," *PNAS* **88**(16): 7276-7280.
46. Ruano, G. et al. (1990) "Haplotype of multiple polymorphisms resolved by enzymatic amplification of single DNA molecule," *PNAS* **87**:6296-6300.
47. Shera, E.B. et al. (1990) "Detection of single fluorescent molecules," *Chemical Physics Letters* **174**(6): 553-557.
48. Syvanen, A. C. et al. (1990) "A primer-guided nucleotide incorporation assay in the genotyping of apolipoprotein-E," *Genomics* **8**(4): 684-692.
49. Landegren, U. et al. (1988) "A Ligase-mediated gene detection technique," *Science* **241**(4869): 1077-1080.

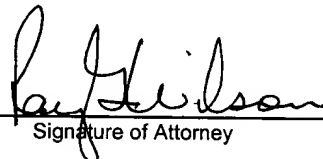
This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional matter material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art under 35 U.S.C. 102.

It is requested that the above citations be made of record in the prosecution of this application.

Respectfully submitted,

Date: July 20, 2001

Reg. No. 28,351
Phone (505) 665-3112



Signature of Attorney

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Los Alamos National Laboratory
LC/BPL, MS D412
Los Alamos, New Mexico 87545



Revised 02/20/01

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Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. S-94,652	Serial No.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant(s) Peter M. Goodwin	
		Filing Date	Group

37 CFR 1.98(b)

U.S. PATENTS DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
	6 1 8 3 9 5 8	02/06/01	Stanton, Jr.	435	6	05/06/98
	6 0 0 4 7 4 4	12/21/99	Goelet et al.	435	5	10/11/91
	5 2 7 4 2 4 0	12/28/93	Mathies et al.	250	458.1	02/24/92
	5 4 3 6 1 3 0	07/25/95	Mathies et al.	436	6	10/26/93
	5 6 5 2 0 9 9	07/29/97	Conrad	435	6	08/18/94
	5 6 5 4 4 1 9	08/05/97	Mathies et al.	536	25.4	02/01/94

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	COUNTRY	CLASS	SUB CLASS	Translation YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

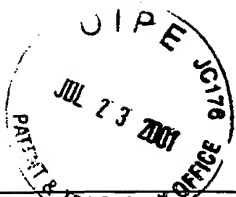
	Cai et al., (2000) "Flow cytometry-based minisequencing: A new platform for high-throughput single-nucleotide polymorphism scoring," <i>Genomics</i> 66 , 135-143.
	Davidson S. (2000) " Research suggests importance of haplotypes over SNPs" <i>Nat. Biotech.</i> 18 : 1134-1135.
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	Taton, T.A. et al. (2000) "Haplotyping by force." <i>Nature Biotechnology</i> 18 : 713-713.
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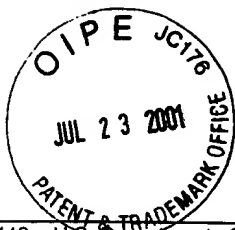
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	Kwok P. (1999). "Single nucleotide polymorphism libraries: Why and how are we building them?" <i>Molecular Medicine Today</i> 5 :538-543.		
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	Schwille, P. et al. (1997) "Dual-color fluorescence cross-correlation spectroscopy for multicomponent diffusional analysis in solution" <i>Biophysical Journal</i> 72 : 1878-1886.				
	Goodwin, P. M. et al. (1996). "Single-molecule detection in liquids by laser-induced fluorescence," <i>Accounts of Chemical Research</i> 29 (12): 607-613.				
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	Egholm, M., et al. (1993) "PNA hybridizes to complementary oligonucleotides obeying the Watson-Crick hydrogen bonding rules" <i>Nature</i> 365 : 566-568.				
	Zhang L. (1992) "Whole genome amplification from a single cell: Implications for genetic analysis," <i>PNAS</i> 89 :5847-5851.				
	Holland, P. M. et al. (1991) "Detection of specific polymerase chain-reaction product by utilizing the 5'-3' exonuclease activity of <i>Thermus-Aquaticus</i> DNA-polymerase," <i>PNAS</i> 88 (16): 7276-7280.				
	Ruano, G. et al. (1990) "Haplotype of multiple polymorphisms resolved by enzymatic amplification of single DNA molecule," <i>PNAS</i> 87 :6296-6300.				
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